APR - 4 2001

K010737

SUMMARY OF SAFETY AND EFFECTIVENESS

COMPANY

Medtronic, Inc.
Medtronic Cardiac Surgical Products
620 Watson Street S.W.
Grand Rapids, MI 49504

CONTACT PERSON

Marie Holm
Associate Product Regulations Manager
Medtronic Perfusion Systems
7611 Northland Drive
Minneapolis, MN 55428
Tel: 763-391-9183
FAX: 763-391-9603

DEVICE NAME

Select CAP™ Arterial Cannula with Pressure Monitoring Line (788XX and 789XX Series)

NAME OF PREDICATED OR LEGALLY MARKETED DEVICE

Arterial Cannula (K840002)
Aortic Root Cannula with Pressure Monitoring Line (K831591)

DESCRIPTION OF DEVICE

The Select CAP™ Arterial Cannula with Pressure Monitoring Line is designed for use in perfusion of the ascending aorta during cardiopulmonary bypass.

The Select CAP™ Arterial Cannula with Pressure Monitoring Line is equipped with a pressure monitoring line, which allows measurement of central arterial pressure.

STATEMENT OF INTENDED USE

The Select CAP™ Arterial Cannula with Pressure Monitoring Line is intended for use in perfusion of the ascending aorta during cardiopulmonary bypass.

STATEMENT OF INTENDED USE OF PREDICATED/MARKETED DEVICE

The Arterial Cannula is intended for use in perfusion of the ascending aorta during cardiopulmonary bypass.

STATEMENT OF TECHNOLOGICAL CHARACTERISTICS COMPARISON

Information regarding technological characteristics comparison is provided in the following section, "Determination of Substantial Equivalence".

DETERMINATION OF SUBSTANTIAL EQUIVALENCE

This **"SPECIAL 510(k)"** is being submitted for a modification to the Arterial Cannula. The modification to the current Arterial Cannula is to include a pressure monitoring line.

The Select CAP™ Arterial Cannula with Pressure Monitoring Line is being compared to the following Marketed Devices:

- Arterial Cannula (K840002)
- Aortic Root cannula(s) with Integral Pressure Monitoring Line (K831591)

The Select CAP™ Arterial Cannula with Pressure Monitoring Line has the same indications statement and intended uses as the:

- Arterial Cannula (K840002)

The Select CAP™ Arterial Cannula with Pressure Monitoring Line has no new technological characteristics (e.g. materials and manufacturing processes). The technological characteristic of the pressure monitoring line is common to other cannula currently in commercial distribution as follows:

- Aortic Root Cannula with Integral Pressure Monitoring Line (K831591)

This technological characteristic "could affect the safety and effectiveness of the device". However, this technological characteristic does not raise new types of safety or effectiveness questions. In addition, "there are acceptable scientific methods which exist for assessing effects of this technological characteristic".

"Performance data to assess the effects of this technological characteristic" has been performed. These "performance data demonstrate" that the Select CAP™ Arterial Cannula with Pressure Monitoring Line is substantially equivalent to other Medtronic marketed cannula.

The biocompatibility and *in vitro* bench testing demonstrated that when compared to the predicate devices, the Select CAP™ Arterial Cannula with Pressure Monitoring Line does not significantly affect safety and effectiveness and are substantially equivalent to other commercially distributed cannula. The *in vitro* bench testing included analysis of: kink testing, clamp testing, flexibility testing, leak testing, burst testing, pull testing and pressure monitoring capability.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR - 4 2001

Medtronic
c/o Ms. Marie Holm
Associate Product Regulations Manager
Medtronic Perfusion Systems
7611 Northland Drive N
Minneapolis, MN 55428-1088

Re: K010737
Trade Name: SELECT CAP™ Arterial Cannula with Pressure Monitoring Line
Regulatory Class: II (two)
Product Code: DWF
Dated: March 09, 2001
Received: March 12, 2001

Dear Ms. Holm:

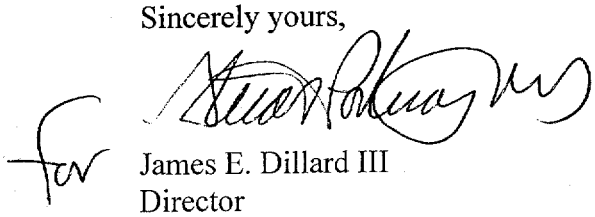
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4648. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,



James E. Dillard III
Director
Division of Cardiovascular and
Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number if known: K010737

Device Name: SELECT CAP™ Arterial Cannula with Pressure Monitoring Line

Indications for Use:

The SELECT CAP™ Cannula with Pressure Monitoring Line is intended for perfusion of the ascending aorta during cardiopulmonary bypass surgery.

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter use ____
(Per 21 CFR 801.109)

43-1

Division of Cardiovascular & Respiratory Devices
510(k) Number K010737